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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,417	07/26/2006	Martinus Antonius Hermanus Maria Wiegerinck	0470-050863	2537

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EXAMINER
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SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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06/27/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,417	<b>Applicant(s)</b> WIEGERINCK ET AL.	
	<b>Examiner</b> Brian Szmaj	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 20-28, 31, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432) in view of Suzuki et al (4,781,699).

Ayre, as discussed above, discloses a cytological sampling instrument and further discloses a tubular means for insertion into a body cavity, the tubular means has a curved distal end, a storage means connected to the tubular means and a vacuum means connected to the storage means and tubular means, the tubular means has a diameter of at least 1cm and has openings only at the curved distal end; a liquid containing means and pump means for expelling the liquid at the distal end of the device; an opening for expelling a liquid from the distal end of the device; the storage means comprise the liquid containing means; the liquid means has a volume of less than 10cc; a sealing means for sealing the openings; the liquid containing means contains a flushing solution (the glycerine solution acts as a flushing solution when expelled from the device when placed at the cervix); the flushing solution is expelled from the device and a sample is introduced in the device. See Column 3, lines 7-10, 17-21, 38-45 and 65-68; and Column 4, lines 7-12 and 38-41.

Ayre however fails to disclose sample openings that are less than 5mm in diameter; the vacuum means comprise a pump means; the vacuum means comprise a plunger-cylinder; and the tube comprises the cylinder.

Suzuki et al disclose a mucus sampling device and further disclose sample openings that are less than 5mm in diameter; the vacuum means comprise a pump means (the plunger acts as a pump); the vacuum means comprise a plunger-cylinder; and the tube comprises the cylinder. See Column 2, lines 20-23, 38-44, 64 and 65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ayre to include the use of small diameter openings as well as a different type of a vacuum source, as per the teachings of Suzuki et al, since it would provide a device that has the ability to obtain a mucus sample utilizing a vacuum source.

3. Claims 29, 30, 32 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432) and Suzuki et al (4,781,699) as applied to claims 20, 31 and 35 above, and further in view of Lurie et al (7,207,951 B1).

Ayre and Suzuki et al, as discussed above, disclose a cervical mucus sampling means, but fail to disclose the vacuum means comprise a plunger in the tubular means, wherein abutment means are provides to define relative movement of the plunger and the tubular means; a biasing means for the plunger; and the flushing solution comprises physiological saline.

Lurie et al, as discussed above, disclose a means for obtaining cell samples and further disclose the vacuum means comprise a plunger in the tubular means, wherein

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abutment means are provides to define relative movement of the plunger and the tubular means; a biasing means for the plunger; and the flushing solution comprises physiological saline. See Column 4, lines 2-11 and 63-65; Column 5, lines 44-67; and Column 6, lines 1-4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ayre and Suzuki et al to include a means of biasing the plunger and utilizing saline as the flush solution, as per the teachings of Lurie et al, since it is well known in the art to utilize a biasing means on the plunger as well as utilizing saline as a flush solution during a medical procedure.

4. Claims 33, 34, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432) and Suzuki et al (4,781,699) as applied to claims 20, 31 and 35 above, and further in view of Oster (3,815,580).

Ayre and Suzuki et al, as discussed above, disclose a means of obtaining a mucus sample, but fail to disclose a kit comprising a closable container for containing the sample, and the container is separate from the sampler; providing a container for transferring the contents of the sampling tube into the container for shipping; and the container is provided with a preserving agent.

Oster discloses a means of preserving cytological samples and further discloses a kit comprising a closable container for containing the sample, and the container is separate from the sampler; and providing a container for transferring the contents of the sampling tube into the container for shipping; and the container is provided with a preserving agent. See Figures 1 and 8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ayre and Suzuki et al to include a kit with a closable container for containing the sample, as per the teachings of Oster, since it is well known in the art to obtain a cell sample and place the sample within a fixative for shipping to a lab.

### ***Response to Arguments***

5. Applicant's arguments filed March 17, 2008 have been fully considered but they are not persuasive.

The Applicants argue Ayres fails to teach a flushing solution, and the disclosed glycerine is not a flushing solution because the glycerine is disposed on the exterior of the device prior to insertion into the vaginal canal. The Examiner respectfully disagrees. Ayre clearly discloses a "charge of glycerine is initially placed within the head during assembling" in Column 3, lines 43-44, and further go on to state the device is placed within the vagina and "the bulb is grasped and squeezed to expel air from the instrument" in lines 65-66. One of ordinary skill in the art would have been able to determine that the charge of glycerine in the head of the device would be expelled in the vagina once the bulb is squeezed, thus acting as a flushing solution.

The Applicants further argue the combination of Ayre and Suzuki et al fail to teach the claims. In particular, Ayre fails to teach openings having a diameter less than 5mm and Suzuki et al fail to teach the size of the openings. Ayre clearly teaches in Column 3, lines 7-8, the shaft is 0.75 inch in diameter, which when converted is 1.9cm.

Based on Figure 2 of Ayre, the openings are clearly smaller than the overall diameter of the device, implying the openings are less than 5mm. Suzuki et al disclose a sampling device where the openings are less than 5mm. Therefore, one of ordinary skill in the art would have been able to utilize openings of less than 5mm, as taught by Suzuki et al, with that of the openings on the distal end of the device of Ayre and yield predictable results. Furthermore, the Applicant argues Ayre "admittedly fails to teach the recited sample openings", and Suzuki et al does not overcome this deficiency because the holes of Suzuki et al are positioned away from the tip, as opposed to at the introduction end. As clearly seen in the above rejection and response, Ayre does clearly disclose the use and positioning of holes at the introduction end, but does not explicitly disclose the size of the holes. Suzuki et al remedies this deficiency through the disclosure of holes on a sampling device with diameters of less than 5mm.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Ayre discloses the use of a sampling device with all of the claim limitations except for the size of the sampling holes at the distal end of the device. Suzuki et al discloses a sampling device and further discloses the size of the holes for sampling.

In response to applicant's argument that Ayre and Suzuki et al are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Ayre discloses a sampling device for placement within a vagina, while Suzuki et al also discloses the use of a sampling device that is placed within a vagina.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmál whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmál/  
Patent Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736